No. 03-1237

In the Supreme Court of the United States

MERCK KGAA,

Petitioner,

v.

INTEGRA LIFESCIENCES I, LTD. AND THE BURNHAM INSTITUTE,

Respondents.

On Writ of Certiorari
to the United States Court of Appeals
for the Federal Circuit

Brief of *Amicus Curiae*, Benitec Australia Ltd. in Support of Integra Lifesciences I, Ltd. and The Burnham Institute

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AMICUS CURIAE BRIEF OF BENITEC AUSTRALIA, LTD.

Pursuant to Supreme Court Rule 37.3(a), on written consent of all parties filed with the Court concurrently with this submission, Benitec Australia, Ltd. ("Benitec") respectfully submits this brief as *amicus curiae* in support of respondents Integra Lifesciences I, Ltd. and The Burnham Institute.[1]

INTERESTS OF *AMICUS CURIAE*

Benitec is an Australian biotechnology company with its primary research, development, and clinical operations centered in Mountain View, California. Benitec has been a pioneer in RNAi technology since 1994 and was the first company to trigger RNAi in human cells and in live animals. RNAi is a cellular mechanism that selectively negates the expression of any gene by destroying messenger RNA, the courier that delivers instructions from a gene to the site of protein production. The existence and functionality of RNAi was set forth in *Science* magazine as the invention (discovery) of the year in 2002 and 2003.

Benitec's DNA-directed RNA interference (ddRNAi) technology is unique in its capability in developing treatments for major diseases such as HIV/AIDS, HCV and other chronic viral infections, cancers, and autoimmune diseases. Benitec's proprietary ddRNAi technology offers significant competitive advantages when used in disease modeling in vitro and in vivo, target validation in vitro and

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1 Pursuant to Rule 37.6, *amicus curiae* states that no person or entity other than Benitec or its counsel has made any monetary contribution to the preparation or submission of this brief. Further, no counsel for Petitioner or Respondent authored this brief in whole or in part.

in vivo, and in high-throughput functional genomics. As such, Benitec's proprietary technology increasingly plays a key role in the identification and development of life-saving new therapeutics. The expansion that petitioner Merck KGaA ("Merck") seeks in the safe harbor of Section 271(e)(1) directly affects Benitec and many similarly situated companies.

SUMMARY OF THE ARGUMENT

This case is not just about statutory construction and Congressional intent. It is also about the harm to patentees if this Court adopts the expansion Merck seeks in the safe harbor of Section 271(e)(1). Merck does not propose *de minimis* infringement but a non-infringement safe harbor for activities related to not only FDA approval of new drugs but also the identification, development, and submission of new drugs to the FDA. Section 271(e)(1) may not be elegantly drafted, but the language and intent behind Section 271(e)(1) is surely directed to the development and submission of information to the FDA and not to the identification, development, and submission of new drugs to the FDA -- *i.e.*, work performed in advance of regulatory submissions and/or the identification of a target for which regulatory approval may ultimately be sought.

Merck and the other safe harbor expansionists promote their objective by generalizing the language of Section 271(e)(1) and by generalizing the activity they want to protect. From the perspective of the infringer, any activity to identify and develop a new drug for submission to the FDA is protected. From an objective perspective, like that of a judge or juror, all infringement is not protected under Section 271(e)(1), even if the infringer argues that it considered the activity included. While information generated when identifying and developing a new drug might ultimately be presented to the FDA, the primary

purpose of the activity is not to develop and submit information to the FDA but to research, identify, characterize, and develop new drug candidates. Most of the information generated in the research, discovery and development phases will not be presented to the FDA.

The vast majority of putative new drugs identified and characterized are not submitted for FDA approval. Indeed, it is only about 1 in 1000 identified and developed new drugs are submitted to the FDA for human testing and regulatory approval. In those few instances when regulatory approval is sought, information generated from only a portion of the overall activity undertaken by drug makers to research, identify, characterize, and develop new drugs is presented to the FDA. Following the initial research, identification, and development phases, Section 271(e)(1) then allows drug makers to avoid infringement liability while generating information intended to be submitted to the FDA for the purposes of seeking regulatory approval. The fact that in some instances a small amount of information generated on a small percentage of putative drug compounds may be submitted along with the data actually generated for the specific purpose of seeking regulatory approval hardly seems compelling enough to ignore the actual purpose of a large portion of infringing activity, ignore the plain language of Section 271(e)(1), and ignore the rights of patentees.

For these reasons and those provided herein, this Court should affirm the Federal Circuit's decision in *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003).

ARGUMENT

IDENTIFYING, CHARACTERIZING, AND DEVELOPING NEW DRUGS THE FDA REGULATES DOES NOT CONSTITUTE ACTIVITY ENTITLED TO THE SAFE HARBOR OF SECTION 271(e)(1).

A. The safe harbor of Section 271(e)(1) is not a subjective right to infringe; limitations are imposed consistent with the reasons for the safe harbor and to protect patentees.

As this Court stated in *Eli Lilly & Co. v. Medtronics, Inc.*, no interpretation of Section 271(e)(1) can turn it "into an elegant piece of statutory draftsmanship." 496 U.S. 661, 679 (1990). Nonetheless, this Court should not construe it as granting infringers a subjective right to freely infringe the patent rights of others when researching, identifying and developing new drugs. Congress enacted Section 271(e)(1) to remedy *de facto* patent term extensions produced by the FDA's approval process and to address the Federal Circuit's decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858 (Fed. Cir. 1984). *Eli Lilly*, 496 U.S. at 670.

The FDA's approval process can produce a *de facto* patent term extension when products that will compete in the market with a patented product must await FDA approval, often delaying the practical value of the patent grant and vitiating the patentee's rights. Because the FDA's approval process is not instantaneous, the patented product enjoys a continued monopoly in the market until the FDA approves competing products for the market. An even lengthier *de facto* patent term extension may result in some cases because of delays associated with the manufacture and distribution of competing products after receiving FDA approval.

In *Roche*, the Federal Circuit had an opportunity to remedy the problem of *de facto* patent term extension as it applied to patented drugs and generic equivalents. *See* 733 F.2d at 860 ("At stake in this case is the length of time a pharmaceutical company can have exclusive access to the American market for the drug."). Roche Products, Inc. ("Roche") owned the patent covering the active chemical compound, flurazepam hydrochloride ("flurazepam HCl"), in its brand name prescription sleeping pill, "Dalmane." *Id.* Before Roche's patent covering flurazepam HCl expired, Bolar Pharmaceutical Co., Inc. ("Bolar"), a generic drug maker, obtained five kilograms of flurazepam HCl from a foreign manufacturer to use for the purpose of developing stability data, dissolution rates, and bioequivalency information to submit in a New Drug Application. *Id.* Roche brought suit to enjoin Bolar's use of flurazepam HCl for this purpose until Roche's patent covering flurazepam HCl expired. *Id.* Although the District Court did not find Bolar's required FDA activity infringing, the Federal Circuit disagreed. *Id.* at 861, 867.

After *Roche*, Congress enacted Section 271(e)(1) to remedy the *de facto* patent term extension problem not only as it applied to brand name patented drugs/generic equivalents but also as it applied in the context of all competing products.

The history leading to Section 271(e)(1) evidences an inherent tension that exists between the patent laws and the FDA regulatory process. Nonetheless, Merck and the other safe harbor expansionists would have this Court expand the safe harbor of Section 271(e)(1) even farther to facilitate not only the FDA's approval process but also the research, identification, characterization and development of new drugs well in advance of the preparation of submissions to the FDA. This Court should decline to do so for at least two compelling reasons.

First, there is no indication in the plain language of Section 271(e)(1) or its legislative history that Congress enacted that statutory provision so that drug makers can research, identify and develop putative new drugs which may someday be submitted to the FDA for regulatory approval. There is no guarantee that a putative new drug made by Merck or any other drug maker will be submitted to the FDA for approval. Most putative new drugs are not submitted to the FDA for approval. *See* C.P. Adams and V.V. Brantner, FTC 2003 White Paper: *New Drug Development: Estimating Entry from Human Clinical Trials* at 8 (Only 1 in 1000 new drugs are subject to human testing for FDA approval.).

Second, the safe harbor of Section 271(e)(1) should not excuse infringement because an infringer subjectively concludes that his drug research, identification, characterization, and development activities ***may*** provide information that at some point in the future may be submitted to the FDA.

The infringer's subjective desire to ultimately obtain FDA approval is not the perspective from which the test of Section 271(e)(1) applies. If such a perspective were adopted, all research and development work would arguably be immune from infringement liability, thereby vitiating a patentee's rights in their entirety. If the infringer's perspective controls, then a patentee within the reach of Section 271(e)(1) would have few, if any, remaining rights to enforce against drug manufacturers. To an alleged infringer, any activity to identify and develop a new product for submission to the FDA could arguably be immune. In no aspect of patent law does an infringer have the right to unilaterally determine whether infringement of another's intellectual property rights is immune from liability, and there is nothing in the plain language of Section 271(e)(1) or its legislative history that provides such immunity or

indicates such a Congressional intent to depart from well-settled law in this respect. To the contrary, Congress set forth an objective test in Section 271(e)(1) for the fact-finder to apply. Specifically, Congress provided that an otherwise infringing act will not constitute patent infringement if, and only if, the otherwise infringing activity is undertaken "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." 35 U.S.C. § 271(e)(1).

This Court and many other courts have had occasion to consider the safe harbor of Section 271(e)(1). To the knowledge of Benitec and its counsel, no court has construed its statutory language as a subjective right to infringe. It defies logic and good sense to look at the infringer's ultimate goal of FDA approval and conclude that activity related to researching, identifying, characterizing, and developing any product is within the safe harbor provisions of Section 271(e)(1). This is not the test Congress set forth in Section 271(e)(1).

If this Court adopts the interpretation Merck seeks, many patentees will have no patent rights to assert against new drug makers at any point during the drug research, identification, and development process. Of course, all drug manufacturers hope that each project they undertake will result in a viable new drug, however very few do and during the discovery process, many patented methods and products can be used. It is highly doubtful that Congress meant to immunize new drug developers from the rights of certain patentees with respect to the entire new drug research, identification, and development process. The opposite is more likely the case. The risk associated with infringing the intellectual property rights of others is placed where it is in other areas of the patent system, with the infringer. The

infringer's subjective desires and goals are not factors in the test Congress set forth in Section 271(e)(1).

The government's *amicus curiae* brief suggests all activity is within the safe harbor of Section 271(e)(1) as soon as a researcher "attempt[s] to develop a substance with specific characteristics in order to achieve a specific objective." (*Amicus Curiae* Brief for the United States at 17). Thus, the government argues that merely having the wish to discover a compound with certain beneficial qualities should shield researchers from infringement. The government's position, however, overbroadly insulates nearly all research from infringement because a researcher can always claim to be searching for some type of vaguely beneficial function or an as yet unknown or uncharacterized drug. The government's advocated standard does not even qualify for "conception" of a medical compound. *Fiers v. Revel*, 984 F.2d 1164, 1169-70 (Fed. Cir. 1993). The FDA does not regulate concepts -- it regulates drugs that have been identified, characterized and developed to the extent that they are ready to enter into the FDA approval process.

The actions of a drug maker to research, identify and develop new drugs that may later be submitted to the FDA is infringement. Similarly, testing a putative new drug to determine if it or one of its derivatives (a different new drug and different concept) might one day be worth submitting to the FDA regulatory process is infringement. Such activity is undertaken to identify and develop new drugs, not to develop information for the FDA's regulatory review. The process of identifying and developing new drugs to submit to the FDA should not be placed on a continuum with the basic research of identifying and developing possible new drugs. The goal of the FDA approval should not become an infringer's ticket to a limitless Section 271(e)(1) safe harbor, nor is it a finish line that if sought or obtained provides unlimited freedom and opportunity to infringe any patent. From an objective

point of view, many infringing activities associated with new drug identification and development before and during the FDA's approval process are not undertaken "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." 35 U.S.C. § 271(e)(1). As such, those activities are not afforded the immunity from liability conferred by the statute's safe harbor provision.

B. Infringement to identify and develop new drugs is not *de minimis*, interferes substantially and selectively with the rights of certain patentees, undermines fundamental principles of the patent system, and contradicts international patent agreements.

One way for new drug makers to save money is to infringe patents while attempting to research, identify, characterize, and develop new drugs to submit to the FDA. Such infringement avoids the need to pay license fees owed to the patentee. 35 U.S.C. § 284. If the safe harbor provision of Section 271(e)(1) immunizes infringement from the earliest steps of the drug development process, the value of patent protection under the patent system is virtually meaningless for many patentees. Infringement occurring while attempting to identify and develop new drugs is not *de minimis* but extensive. The value of some patented technologies -- particularly patents related to screening methods and research reagents -- only exists in their applicability to the drug identification, characterization, and/or development process.

For example, the expanded safe harbor advocated by Merck and the other safe harbor expansionists would severely impact patentees of method patents in the

biotechnology arena. Many biotechnology method patents may be used to test and characterize potential therapeutics. Drug makers test and characterize potential therapeutics at many stages in the drug identification and development process, not just at the end when FDA approval is sought. As the value derived from Polymerase Chain Reaction ("PCR") methodologies and patents has taught, and as *Integra* illustrates, method patents such as assays for target validation and drug screening are powerful technologies and are important business assets. The primary value of these technologies comes from activities occurring prior to submission of a new drug to the FDA. Many companies such as Benitec derive substantial value from the ability to license their intellectual property for these purposes. Benitec and other similarly situated companies should be able to rely on having the same rights for patent protection under the United States patent system as are afforded to patentees of other technologies. The same is true for research reagents, products whose usefulness is limited to the drug discovery process. Without the constitutional protections provided by the patent statute, little motivation would exist to create these critical methods or reagents.

Expansion of the safe harbor also undermines one of the principles of patent law. If the safe harbor of Section 271(e)(1) is expanded in the way Merck and the other safe harbor expansionists suggest, companies will not choose to patent developed methodologies because patent protection will not provide competitive advantage. An expanded safe harbor will enable others to infringe freely, thus diminishing the value of the technology. In turn, companies will choose to retain methodologies as trade secrets instead of seeking patent protection. Sequestering technological information in such a way is the opposite of the stated goal of the patent system, which is to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and

Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. I, § 8, cl. 8. The progress of science, including the progress of research tools and methodologies drug makers use to identify and develop new drugs, depends on the incentive of exclusivity for a limited period of time.

Merck and the other safe harbor expansionists would have this Court consider the sometimes difficult, costly, and lengthy process by which new drugs are identified and developed as a justification for construing Section 271(e)(1) as a safe harbor for their drug identification and development activity. Many new technologies were also difficult, costly, and lengthy to develop and patent, including those that new drug makers want to infringe.

Not only would Merck's expansive safe harbor undermine the goals of the patent system, but it would also contradict international patent agreements. Expansion of 35 U.S.C. § 271(e)(1) to encompass research screening used to identify and develop a new drug to submit to the FDA would render patent protection for pharmaceutical screening methods impossible. The Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15. 1994, 33 I.L.M. 81 ("TRIPS"), extends the General Agreement on Trade and Tariffs ("GATT"), Oct. 30, 1947, 61 Stat. A-11, T.I.A.S. 1700, 55 U.N.T.S. 194, to patents. Article 27(1) of TRIPS precludes discrimination regarding patent protection for any field of technology.

Failure to provide meaningful patent protection for pharmaceutical screening methods and other research tools treats these technologies in a discriminatory manner, thereby violating United States commitments under TRIPS/GATT. While treaty compliance does not supersede laws passed by Congress, when possible, laws should be construed to satisfy treaties. *Murray v. Schooner Charming Betsy*, 2 Cranch 64,

118, 2 L.Ed. 208 (1804) (Marshall, C.J.) ("[A]n act of congress ought never to be construed to violate the law of nations if any other possible construction remains."). Here, adopting the position advocated by Merck and the other safe harbor expansionists would be discriminatory and actionable in the World Trade Organization. *See, e.g.*, Canada-Patent Protection of Pharmaceutical Products, 2000 WL 301021, Doc. WT/DS114/R (Mar. 17, 2000) (finding discrimination as to the field of technology in the context of stockpiling pharmaceutical products six months before the patent term ended, despite a lack of sales to consumers during that period.).

C. After-the-fact use of some information generated when identifying and developing the handful of new drugs submitted to the FDA for approval does not negate the actual purpose of the activity nor justify placing the activity in the safe harbor of Section 271(e)(1).

Whether information is submitted to the FDA after-the-fact should not negate the actual purpose of the activity nor justify placing the activity in the safe harbor of Section 271(e)(1). It is far too easy for an infringer to conceal infringing activities in paperwork presented to the FDA or find protection in the ambiguity of activities undertaken well in advance of entering the FDA approval process. Nowhere does Section 271(e)(1) provide that activity is within the safe harbor simply because the infringer may choose to present some information to the FDA. Section 271(e)(1) requires more, patentees deserve more.

Patentees deserve the right to derive value from their patents notwithstanding Section 271(e)(1). The FDA is not interested in everything applicants do prior to and during the FDA's approval process. For example, the FDA is not

interested in the hundreds or thousands of drug candidates screened or information generated from every conceivable animal study an infringer may consider desirable in the hunt for a new drug. Similarly, all animal studies that a new drug maker finds desirable are not undertaken to develop and submit information to the FDA. Some animal studies are conducted to research, identify, characterize and/or develop new drugs to submit to the FDA. Placing otherwise infringing activity in the safe harbor of Section 271(e)(1) because an infringer chooses to present some information generated from the activity to the FDA does not temper the affect it has on the rights of patentees and the patent system or *ipso facto* render the activity of the sort contemplated by Congress in enacting Section 271(e)(1).

Access to patented technologies to research, identify, characterize, or develop new drugs may be had through licensing such as that occurring in virtually every other field of technology. Although in a brand name patented drug/generic equivalent situation, generic drug makers were likely foreclosed from licensing the patents they needed to obtain FDA approval. This is largely not the case for drug developers using patented methodologies. Such method patents most often belong to patentees who do not directly compete with drug makers' products. These patentees, unlike brand name drug patent holders, are willing to license their technology to derive revenue from drug companies through annual technology access payments, milestone payments, and/or royalties from product sales on identified, characterized, developed, and FDA approved drugs.

D. New drug makers can generate the same information for FDA approval without infringement to research, identify and develop new drugs.

Once a drug maker identifies, characterizes and develops a new drug, the new drug may not be marketed for human consumption without the approval of the FDA. Like with all things the FDA regulates, information for FDA approval can only be generated after the thing to be regulated exists. The FDA does not approve new drugs for human consumption before they are identified and developed. So too, the FDA approval process does not delay unidentified and undeveloped new drugs from entering the market. There is a difference between the experiments and tests drug makers subject new drugs to for FDA approval and the experiments and tests drug makers conduct to identify and develop new drugs to submit to the FDA.

Nearly every experiment and test a drug maker conducts on the underlying biological basis of human disease and suffering has a common goal -- the identification and development of a new drug to submit to the FDA for human consumption. For example, the experiments and tests at issue below were not for FDA approval but were designed to answer general questions pertinent to the study of any new drug or biologic:

> As summarized by Merck, Dr. Cheresh testified that the purpose of the research was to "(1) assess the potential efficacy of the peptides as therapeutic agents; (2) discovery the mechanism of action of the peptides; and (3) shed light on histopathology, toxicology, circulation, diffusion, and half-life of the peptides in the bloodstream." Brief at 15. The ultimate goal of the research was undisputed: it was to find a product that would be sufficiently effective in the treatment of angiogenic disease that it could be developed and brought to market for this purpose.

Integra, 331 F.3d 874 (Newman, J., dissenting). Merck was trying to research, identify, characterize, and develop a new drug and derivatives (more new drugs) to submit to the FDA.

The experiments and testing by Merck at issue in *Integra* and those done by nearly all drug makers to research, identify, characterize, and develop a new drug include, for example, modifications to the structure of molecular entities, comparative investigations of properties of modified entities, receptor binding assays, functional assays, mechanism of action studies, pharmacokinetics, cell studies, animal studies, chick embryo studies to obtain pharmacokinetic data, and the like. To include such activities in the safe harbor of Section 271(e)(1) no matter how attenuated from the FDA's approval process will essentially exempt all biomedical experiments and testing from infringement liability.

Merck, however, and the other safe harbor expansionists, point to no FDA regulation that cannot be satisfied after a new drug is identified, developed, and submitted to the FDA. For example, the information to satisfy 21 C.F.R. §§ 314.50(d)(2)(i) ("the pharmacological action of the drug in relation to its proposed therapeutic indication and studies that otherwise define the pharmacologic properties of the drug") and 314.50(d)(2) ("the absorption, distribution, metabolism, and excretion of the drug in animals") can be generated after a new drug is identified, characterized, developed, and submitted to the FDA. The Federal Circuit likely recognized this when it addressed the fact-sensitive question that it did in *Integra*:

> [W]hether the pre-clinical research under the Scripps-Merck agreement is exempt from liability for infringement of Integra's patents under § 271(e)(1).

Integra, 331 F.3d at 865. Given that there is a difference between infringement undertaken to develop and submit information to the FDA and infringement undertaken to identify and develop new drugs to submit to the FDA, the Federal Circuit answered the question correctly:

> The Scripps-Merck experiments did not supply information for submission to the United States Food and Drug Administration (FDA), but instead identified the best drug candidate to subject to the future clinical testing under the FDA processes.

Id.

In using the term "clinical" in *Integra*, the Federal Circuit was not invoking the hyper technical use of that term found in FDA parlance. Although Merck and the other safe harbor expansionists focus nearly exclusively on the word "clinical" in the above quote, the Federal Circuit's decision to use this word should not be interpreted as anything more than a conclusion that Merck's activity was not undertaken "solely for uses reasonably related to the development and submission of information . . . under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." 35 U.S.C. § 271(e)(1).

CONCLUSION

This Court should affirm the Federal Circuit's decision in *Integra* and find that Section 271(e)(1) does not provide for infringement to research, identify, characterize, and develop

new drugs to submit to the FDA for approval. *See* 35 U.S.C. § 271(e)(1).

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